UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,161	03/12/2004	Rebecca M. Cade	31089USCIP	9021

22847 7590 10/30/2006

SYNGENTA BIOTECHNOLOGY, INC.
PATENT DEPARTMENT
3054 CORNWALLIS ROAD
P.O. BOX 12257
RESEARCH TRIANGLE PARK, NC 27709-2257

EXAMINER	
KUBELIK, ANNE R	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/800,161	CADE ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-12 and 16-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,5-12 and 16-21* is/are allowed.

6)☒ Claim(s) *22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 5-12 and 16-24 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The objections to claims 2-4 and 12 to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form are withdrawn in light of Applicant's cancellation or amendment of the claims.

4. The rejection of claims 11 and 13-21 under 35 U.S.C. 102(b) as being anticipated by Ryals et al (1997, US Patent 5,689,044) is withdrawn in light of Applicant's amendment of the claims.

Claim Rejections - 35 USC § 112

5. Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Neither the instant specification nor the originally filed claims appear to provide support for a claim to a nucleic acid comprising a fragment of SEQ ID NO:24 that comprises SEQ ID NO:26 or 28. The specification on pg 6, lines 5-11, when discussing fragments only mentions SEQ ID NO:26 and 28, not larger fragments comprising these sequences.

Thus, such a claim constitutes NEW MATTER. In response to this rejection, Applicant is required to point to support for the phrase or to cancel the new matter.

6. Claims 22-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for promoters of SEQ ID NO:24-28, does not reasonably provide enablement for a promoter with 99% identity to SEQ ID NO:24-28. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is different from the rejection of set forth in the Office action mailed 20 March 2006, as applied to claims 11 and 13-21, due to Applicant's amendment of the claims. Applicant's arguments filed 14 August 2006 have been fully considered but they are not persuasive.

The claims are broadly drawn to promoters with 99% identity to SEQ ID NO:24-28.

The instant specification, however, only provides guidance for SEQ ID NO:s 25-27.

The specification does not teach how to make promoters with 99% identity to SEQ ID NO:24-28.

The region of a given promoter that has a specific activity cannot be predicted and involves the complex interaction of different subdomains (Benfrey et al, 1990, Science 250:959-966, see Abstract, Fig. 3-5). Even a very small region may be critical for activity, and the criticality of a particular region must be determined empirically (Kim et al, 1994, Plant Mol. Biol. 24:105-117, Tables 1-4, Abstract, Fig. 1-2). The instant specification does not teach which regions are crucial for pathogen or SAR-induction chemical inducibility.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate

promoters with 99% identity to SEQ ID NO:24-28. Making all possible single nucleotide substitutions in the 962 nucleoitde-long SEQ ID NO:24 would require making and analyzing 4^{962} (1.52×10^{579}) nucleic acids. Because nucleic acids with 99% identity to SEQ ID NO:24 would have 9 nucleic acid substitutions, many more than 1.52×10^{579} nucleic acids would need to be made and analyzed. Thus, making and analyzing nucleic acids with 99% identity to SEQ ID NO:24-28 that also have promoter activity would require undue experimentation.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate promoters with 99% identity to SEQ ID NO:24-28.

Given the claim breath, unpredictability in the art, and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

Applicant urges that making and using the claimed invention will not require undue experimentation since confirmation of promoter function and be done according to the specification (response pg 6).

This is not found persuasive because the lack of guidance in the specification as to which nucleotide substitutions to make in the SEQ ID NOs: 24-28 means that trail and error experimentation must be used. Because of the larger number of possible substitutions that can be made, that experimentation is undue.

Applicant urges that pg 11-14 provide enablement, as does Example 19 (response pg 6).

This is not found persuasive because pg 11-14 provides definitions, and describes programs for determining protein identity, but do not teach which nucleotide substitutions to make. Example 19 provides assays but does not teach which nucleotide substitutions to make.

7. Claims 22-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is different from the rejection of set forth in the Office action mailed 20 March 2006, as applied to claims 11 and 13-21, due to Applicant's amendment of the claims. Applicant's arguments filed 14 August 2006 have been fully considered but they are not persuasive.

The claims are broadly drawn to promoters with 99% identity to SEQ ID NO:24-28. SEQ ID NO:24 is not known in the art nor are fragments of it that have promoter activity. The specification does not describe any motifs that confer promoter activity to SEQ ID NO:24. The only species reduced to practice are SEQ ID NOs:25-27. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, one of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species.

Hence, Applicant has not, in fact, described promoters with 99% identity to SEQ ID NO:24-28 within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed compositions, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

Applicant urges that claims 22-23 require pathogen or SAR-induction chemical inducibility (response pg 6).

This is not found persuasive because the instant specification does not describe crucial for pathogen or SAR-induction chemical inducibility.

Applicant urges that pg 11-14 provide written description, as does Example 19 (response pg 6).

This is not found persuasive because pg 11-14 provides definitions, and describes programs for determining protein identity, but do not describe the structural features that distinguish promoters with 99% identity to SEQ ID NO:24-28 from other nucleic acids with 99%identity to SEQ ID NOs:24-28. Example 19 provides assays but does not describe the claimed structures.

8. Claims 1, 5-12 and 16-21 are allowable.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne Kubelik, Ph.D.
October 25, 2006

ANNE KUBELIK, PH.D.
PRIMARY EXAMINER